

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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TITLE: ANKLE BRACE

SPECIFICATION

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

The present invention relates to an ankle brace device, and specifically to an ankle brace that is easily put on and minimizes interference with walking.

RELATED ART

Ankle orthoses have become a standard treatment for orthopedic foot and ankle problems. Most are bulky and entirely rigid. Typically, a plurality of straps are required for attachment about the foot and ankle. These devices are cumbersome and time-consuming to apply and diminish proprioception while ambulating because the heel is covered by the device. Further, these devices are difficult to wear with standard footwear, leaving an individual self-consciously wearing only one shoe and an unsightly brace.

What is needed, but has not yet been provided, is an ankle brace which is easy to put on, which provides necessary support, which provides a comfortable fit, and which allows for easy walking.

SUMMARY OF THE INVENTION

The present invention provides an ankle brace having a rigid member that extends under a foot and up along sides of an ankle and lower leg. Inner and outer layers surround the rigid member and form a body. The body has a foot portion including a forward edge defining a toe aperture, a footbed, and a leg portion joined to the foot portion, the leg portion including an upper edge, and rear edges extending from the upper edge to the footbed. The foot portion covers the top of the foot and the leg portion covers the front of the lower leg. A fastening strap is connectable about the leg portion to retain the brace on the foot, ankle and leg of the individual. A flexible heel portion extends from the footbed. A cushion layer can be provided between the inner layer and the rigid member.

The present invention also provides a method for treating an ankle injury using the ankle brace of the invention. The method comprises custom forming a rigid member, incorporating the rigid member in a body having inner and outer layers, inserting a foot, toes first, between rear edges of a leg portion of the body; inserting the toes through a toe aperture; placing the foot onto a footbed portion; fastening a strap about the leg portion to secure the ankle brace to a foot and leg; and wearing the ankle brace on the leg for a sufficient time to treat the injury. The method further includes allowing the heel to flex to facilitate walking.

BRIEF DESCRIPTION OF THE DRAWINGS

Other important objects and features of the invention will be apparent from the following Detailed Description of the Invention taken in connection with the accompanying drawings in which:

FIG. 1 is a front view of the ankle brace of the invention on a foot.

FIG. 2 is a medial side view of the ankle brace of **FIG. 1**.

FIG. 3 is a lateral side view of the ankle brace of **FIG. 1** positioned on a foot.

FIG. 4 is a rear view of the ankle brace of **FIG. 1**.

FIG. 5 is a rear view of the ankle brace of **FIG. 1** positioned on a foot.

FIG. 6 is a rear perspective view of the ankle brace of **FIG. 1** showing a foot entering the rear of the brace.

FIG. 7 is a partial cross-section view of the ankle brace of **FIG. 1** showing the layers comprising the foot portion.

DETAILED DESCRIPTION OF THE INVENTION

The ankle brace of the present invention is provided for stabilizing and/or treating the ankle for ankle injuries and conditions including posterior tibialis tendon dysfunction, Charcot ankle, Achilles tendon rupture and general ankle instability and derangement. The ankle brace can be custom made for each patient. The ankle brace provides support and stability, and controls the motion of an injured foot and ankle by encasing the dorsum of the foot. This ensures proper positioning in the device and better mediolateral control of the ankle and arch of the foot. The ankle brace intimately fits and conforms to the natural skeletal and muscular structure of the foot.

The ankle brace of the present invention is shown in **FIGS. 1-7**. The ankle brace is generally indicated in the **FIGS.** at **10**. The ankle brace comprises a foot engaging portion and a leg engaging portion. The ankle brace **10** includes inner and outer layers forming a boot-shaped body **12** having an open toe, an open back and a flexible heel. A rigid support member **30** is positioned within the inner and outer layers. The rigid support is preferably in the form of a single integral member extending under the foot to form a footbed portion, and extending up along the sides of the ankle and lower leg.

As shown in **FIG. 1**, a foot, ankle, and leg **60** are placed into the ankle brace **10**. The body **12** has a forward edge **14** through which toes **62** of a foot extend. The body includes a foot portion and a leg portion. The foot portion is sized to receive and surround a foot. The foot portion includes a footbed. The leg portion, as will be described, covers the lower front portion of the leg and partially surrounds the leg. The leg portion has an upper edge **16**. Strap **40**

secures the ankle brace to the foot and leg. Outer layer **26** is positioned over the rigid support member **30**.

As can be seen in **FIG. 2**, the ankle brace **10** and rigid member **30** form a footbed **21** which is sized to extend along the bottom of a foot from the ball of the foot, under the arch of the foot, to forward of the heel. The rigid support member **30** extends up the sides of the body **12** to support the inner and outer surfaces of the ankle and lower leg of an individual. The rigid support member **30** is formed of a rigid or semi-rigid material such as plastic.

As can be further seen in **FIG. 2**, the body **12** has a foot portion with forward edge **14**, and a leg portion with a top edge **16** and rear edge **18**. The bottom of the foot portion forms footbed **21**. The footbed **21** includes a flexible heel **20** to facilitate walking. Flexible heel **20** can bend in the direction of arrow **A** when the user of the ankle brace is walking. Outer layer **26** extends over rigid support member **30**, and also forms the bottom of the flexible heel. Strap **40**, along with leg cover **46**, secures the brace about a user's foot, ankle, and leg.

FIG. 3 shows the ankle brace **10** on a foot. The foot portion of body **12** surrounds the foot and ankle. Toes **62** extend past open end **14**. The bottom of the foot sits on footbed **21**. The leg portion covers the front of the lower leg. Upper edge **16** is positioned on leg **60**. Rear edge **19** extends between the upper edge **16** and heel **20**, leaving the back of the heel **61** as well as portions of the back of the leg **60** uncovered by the brace **10**. The rigid support member **30** extends under the foot and up the sides of the body **10**, along the ankle and lower leg, and is covered by outer layer **26**. Strap **40** and leg cover **46** wrap about the leg to retain the brace on

the leg. The strap can be fastened in any known way such as with a hook and loop fastening system. One of the hook or loop elements **42** is positioned on one end of one side of the strap, and the other of the hook and loop fastening system is on the end and other side of the strap.

FIGS. 4 and 5 are rear views of the brace **10**. Inner and outer layers **24** and **26** can be seen, and the rigid member **30** is positioned between the inner and outer layers **24** and **26**. Rear edges **18** and **19** extend along the leg portion of body **12** from the footbed **21** at the heel **20** to upper edge **16**. Leg cover **46** wraps about the leg, and is tucked under edge **19**, and strap **40** extends over the cover about the body and is fastened on itself to hold the brace on the foot and leg, as can be seen in **FIG. 5**.

While a leg cover is not required, it adds comfort to the brace by dissipating the force of the strap when the strap is tightened and secured against the wearer's leg. The leg cover can be securely attached at one end, such as by sewing, onto the body of the brace. It can be attached to the inner layer of the body adjacent to an edge of the open back. It can be made of any suitable material, preferably the same material as the inner and outer layers. The leg cover is positioned over the back of the leg where the securing strap is located. When the brace is applied to the foot and leg, the end of the cover overlaps the opposite edge of the open back of the body of the brace. The strap is then wrapped about the leg over the leg cover and secured. Accordingly, the leg cover protects the leg from the strap.

As shown in **FIG. 6**, the ankle brace **10** is placed on a foot by inserting the foot, toes first, in the direction of arrow **B**, through the open back of the body **12** defined by the rear edges **18**,

19. The toes 62 of the foot are inserted through the open toe of brace 10 so that the foot is in the foot portion of the body 12. The sole of the foot and heel 61 are placed onto the footbed 21 and flexible heel 20. The inner layer 24 bears against the foot, ankle and lower leg, while outer layer 26 can be seen on the exterior. The strap 40 and leg cover 46, if present, are wrapped about the leg 60 and fastened. The rigid member 30 extends under the foot and up along the ankle, and lower leg. The ankle brace is worn on the leg for a time sufficient to treat the injury, or for as long as stabilization of the ankle and leg is required.

A cross-sectional view of the footbed 21 of the ankle brace 10 is shown in FIG. 7. As can be seen, the body 12 includes footbed 21 which comprises an outer layer 26, rigid member 30, cushion layer 22, and inner layer 24. Cushion layer 22 is positioned between the inner layer 24 and the rigid member 30. Cushion layer 22 extends from the forward edge 14 to the rear edge of the flexible heel 20. Outer layer 26 covers the bottom of the rigid member 30. The rigid member 30 extends from proximate the forward edge 14 to adjacent the flexible heel 20. The flexible heel 20 comprises inner layer 24, outer layer 26, and cushion layer 22.

Because the ankle brace provides for rear entry, it is easy to put the brace on the foot and lower leg. Because the front and sides of the brace are uninterrupted, the brace provides for better control of the forefoot and ankle. As the foot is placed in the brace, the ankle slides into proper position, and is controlled by the medial and lateral portions of the rigid support.

The rigid support member comprises a rigid or semi-rigid material such as plastic. Any suitable material, such as a thermoplastic, can be used. The rigid support member can be molded

to the shape of an individual's foot and ankle to provide a custom fit to meet the individual's treatment or stabilization needs. This custom-fitted molding can be performed prior to manufacturing the ankle brace for a patient. A cast of the injured foot is taken and filled with plaster to make a positive model. The plaster model is smoothed and shaped and then the brace is molded over the model. The plastic is heated and becomes more fluid. After it is cooled, the cast is cut off and shaped to the appropriate trim lines. This type of molding process is well known in the art.

The flexible heel leaves a portion of the back of the heel of the foot unsupported by the rigid member. This flexibility, along with the open toe, provides for a more normal and anatomical gait and also allows the brace to be comfortably worn with standard footwear because there is less bulk in the rear and front of the brace. The brace may be worn with or without socks or stockings under or over the brace.

The inner and outer layers encasing the U-shaped support member and forming the boot-shaped body comprise a soft durable material such as leather; however, imitation leather, vinyl or other suitable materials can also be used. The inner and outer layers, as well as cushion layer and the rigid member, can be attached together by an adhesive. A polyadhesive, such as BARGE, has worked successfully. Additionally, the inner and outer layers can be stitched along on the edges of the brace, and at other locations, to reinforce their attachment.

The cushion layer provides a more comfortable fit to the individual by creating a soft barrier between the rigid support member and the individual's foot. The cushion layer may also

be positioned between the inner and outer layers in portions of the brace other than areas where the support member extends to provide overall comfort to the individual wearing the brace. The cushion layer can comprise foam, gel, fiber or non-fiber padding, air bladder or other similar material. An example of suitable foam is a polyethylene closed cell foam such as PLASTAZOTE®, a trademark owned by ZOTEFOAMS, PLC., Surrey, England.

The strap can utilize hook and loop fasteners, buckles or other fastening means. For example, loop material can be provided on the outer side of the end portion of the end of the strap attached to the body, and hook material can be provided on substantially all of the inner side of the strap or only on the inner side of the end portion of the other end of the strap. The strap can be a separate element or can be securely attached, such as by sewing, onto the body of the brace. Preferably the strap is attached to the outer layer of the body adjacent to an edge of the open back in the calf region. The strap can be made of plastic, elastic, leather, cloth, vinyl or other suitable material. Preferably, the strap is made of the same material as the inner and outer layers. If desired, more than one strap may be provided.

The following example illustrates the present invention, but is not meant to limit its scope.

EXAMPLE

The ankle brace of the invention was tested on approximately 102 patients having the following conditions: 72 had posterior tibialis tendon dysfunction, 10 had Charcot ankles, 12 had Achilles injuries, and 8 had chronic ankle instability. The age range of the patients was 14 to 82

years with a mean age of 50. The patients were each fitted with a custom-molded ankle brace of the present invention. The patients wore the braces for approximately 12 hours per day. Patients were examined between 3 to 9 months (mean range 6 months), beginning from the time of first wearing the ankle brace of the present invention. The patients were asked questions about the status of their condition. All but two of the patients showed significant improvement in pain. Approximately 90% of the patients were successfully treated and did not require surgical intervention.

Various details of the invention may be changed without departing from its scope. Furthermore, the foregoing description of the preferred embodiment of the invention and the example are provided for the purpose of illustration only and not for the purpose of limitation, the invention being defined by the claims.